

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-K-0120  
CUSTOMER NUMBER: 20883

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Dynogen Pharmaceuticals  
801 Capitola Drive Suite 12  
Durham, NC 27713

MAR 06 2006

Telephone: (919)-572-1919

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report )	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats			29	3	32
6. Guinea Pigs			6		
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

( NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

(b)(6), (b)(7)c

3/3/06

QC92

## Column E Explanation

Date: 3/2/06

1. Registration Number: 55-R-0120
2. Number of animals used in this study: 3
3. Species (common name) of animal used in this study: cat

4. Explain the procedure producing pain and / or distress:

Surgical spinal cord injury at the lumbo-sacral region leading to paralysis of the lower extremities and bladder dysfunction. Also, weekly repeated isoflurane anesthesia post surgical recovery for five weeks.

5. Provide scientific justification why pain and / or distress could not be relieved. State methods or means used to determine that pain and / or distress relief would interfere with test results.

One area of focus for Dynogen was developing therapeutic treatments for paraplegic and quadriplegic patients with spinal cord injury. Patients with spinal cord injury have disruptive control of urinary function. Through our experiments, we expect to identify drug treatments which will restore aspects of control to urinary function in paraplegic and quadriplegic patients. In order to study this research area a representative model needs to be in place. Cats are often used in this model because, cats, like humans, have a dual control nervous system responsible for urination. Animals were carefully monitored and given analgesics pre and post surgery to alleviate surgical pain. Distress due to repeated isoflurane anesthesia could not be alleviated because all known tranquilizers or other pre-anesthesia sedatives cause disruption to the function of the urinary system.

6. What, if any, federal regulation requires this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Not applicable.

(b)(6), (b)(7)c

3/3/06